

## Food and Drug Administration, HHS

## § 73.2125

are exempt from the certification pursuant to section 721(c) of the act.

[42 FR 33722, July 1, 1977]

### § 73.2110 Bismuth citrate.

(a) *Identity.* The color additive bismuth citrate is the synthetically prepared crystalline salt of bismuth and citric acid, consisting principally of  $\text{BiC}_6\text{H}_5\text{O}_7$ .

(b) *Specifications.* The color additive bismuth citrate shall conform to the following specifications and shall be free from impurities other than those named to the extent that those impurities may be avoided by good manufacturing practice:

Bismuth citrate, not less than 97 percent.

Mercury (as Hg), not more than 1 part per million.

Arsenic (as As), not more than 3 parts per million.

Lead (as Pb), not more than 20 parts per million.

Volatile matter, not more than 1 percent.

(c) *Uses and restrictions.* The color additive bismuth citrate may be safely used in cosmetics intended for coloring hair on the scalp, subject to the following restrictions:

(1) The amount of bismuth citrate in the cosmetic shall not be in excess of 0.5 percent (w/v).

(2) The cosmetic may not be used for coloring eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling.* (1) The label of the color additive bismuth citrate shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(2) The label of a cosmetic containing the color additive bismuth citrate shall bear, in addition to other information required by law, the following statement, conspicuously displayed thereon:

Keep this product out of children's reach. Do not use on cut or abraded scalp. Do not use to color eyelashes, eyebrows, or hair on parts of the body other than the scalp. Wash hands thoroughly after each use.

(e) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health, and, therefore, batches thereof are exempt

from certification requirements of section 721(c) of the act.

[43 FR 44831, Sept. 29, 1978]

### § 73.2120 Disodium EDTA-copper.

(a) *Identity.* The color additive disodium EDTA-copper is disodium [[N,N'-1,2-ethanediylbis[N - (carboxymethyl)glycinato]] (4-)-N,N',O,O',O'',O'''] cuprate (2-).

(b) *Specifications.* Disodium EDTA-copper shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

Total copper, not less than 13.5 percent.

Total (ethylene-dinitrilo) tetracetic acid, not less than 62.5 percent.

Free copper, not more than 100 parts per million.

Free disodium salt of (ethylene-dinitrilo) tetraacetic acid, not more than 1.0 percent.

Moisture, not more than 15 percent.

Water insoluble matter, not more than 0.2 percent.

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

(c) *Uses and restrictions.* Disodium EDTA-copper may be safely used in amounts consistent with good manufacturing practices in the coloring of shampoos which are cosmetics.

(d) *Labeling requirements.* The labeling of the color additive shall conform to the requirements of § 70.25 of this chapter.

(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health and therefore batches thereof are exempt from the requirements of section 721(c) of the act.

### § 73.2125 Potassium sodium copper chlorophyllin (chlorophyllin-copper complex).

(a) *Identity and specifications.* The color additive potassium sodium copper chlorophyllin shall conform in identity and specifications to the requirements of § 73.1125(a)(1) and (b).

(b) *Uses and restrictions.* Potassium sodium copper chlorophyllin may be safely used for coloring dentifrices that